DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 3, 2015

Shenzhen Urion Technology Co., Ltd.
Autumn Liu
Sales Manager
4th Building, Hi-tech Industrial Zone,
Heping Community, Fuyong Street, Baoa
Shenzhen, 518103 CH

Re: K141683
Trade/Device Name: Electronic Blood Pressure Monitor, U60 Series including U60A and U60AH
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: February 16, 2015
Received: February 18, 2015

Dear Autumn Liu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

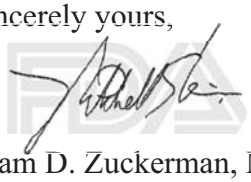
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141683

Device Name
Electronic Blood Pressure Monitor U60 Series, including U60A and U60AH

Indications for Use *(Describe)*

U60 Series Wrist Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K141683

1. Date of Submission: June 19, 2014

2. Sponsor

   Shenzhen Urion Technology Co., Ltd
   4th building, Hi-tech Industrial Zone, Heping Community, Fuyong street, Baoan District, Shenzhen, Guangdong, China 518103

   Establishment Registration Number: Not yet registered;

   Contact Person: Ms. Autumn Liu
   Position: Sales Manager
   Tel: +86-755-29231308
   Fax: +86-755-27493959
   Email: autumn@urion.com.cn

3. Submission Correspondent

   Ms. Autumn Liu
   Shenzhen Urion Technology Co., Ltd.
   4th building, Hi-tech Industrial Zone, Heping Community, Fuyong street, Baoan District, Shenzhen, Guangdong, China 518103
   Tel: +86- 755-29231308
   Fax: +86-755-27493959
   Email: autumn@urion.com.cn

4. Device Identification

Proposed Device Name: Electronic Blood Pressure Monitor;
Proposed Device Model: U60 Series, including U60A and U60AH

Classification Name: Cardiovascular Diagnostic Devices;
Common Name: Electronic Blood Pressure Monitor;
Class: Class II;
Product Code: DXN;
Regulation Number: 21 CFR 870.1130;
Review Panel: Cardiovascular;

Intended Use Statement:
U60 Series Wrist Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm.

5. Predicate Device Identification

510(k) Number: K070826
Product Name: Electronic Blood Pressure Monitor, KD-795
Manufacturer: Kodon (Tianjin) Electronic & Electrical Apparatus Co., Ltd

6. Device Description

The proposed device, U60 Series Wrist Electronic Blood Pressure Monitor, is a battery driven automatic on-invasive blood pressure monitor. It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult person at wrist within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or KPa.

All the models included in this submission follow the same software, same measurement principle and same specifications. The main differences are data storage and time display. These two differences will not affect the safety and effectiveness of the device.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety, and

essential performance.

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

ANSI/AAMI/IEC 80601-2-30:2009 Medical electrical equipment Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.

8. Substantially Equivalent

Table 3-1 Substantially Equivalent Comparison

ITEM	U60 Series Electronic Blood Pressure Monitor	K070826 Electronic Blood Pressure Monitor KD-795,	Comparison
Product Code	DXN	DXN	Same
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	Same
Class	II	II	Same
Intended Use	U60 Series Wrist Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm.	Wrist Measurement Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure diastolic, systolic blood pressure and pulse rate on adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 6.1023 inches to 9.8425 inches.	SE Analysis 1
Measurement Type	Wrist	Wrist	Same
Patient Population	Adult	Adult	Same
Measurement Item	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	Same
Principle	Oscillometric	Oscillometric	Same
BP Range	0 ~ 299 mmHg	0 ~ 300 mmHg	Same
BP Accuracy	±3 mmHg	±3 mmHg	Same
PR Range	40-199 bpm	30-180 bpm	SE Analysis 2
Cuff Size	31 cm (length) x 8.3 cm (width)	30cm (length) x 7 cm (width)	SE Analysis 1
Power Supply	two AAA	two AAA	Same
Software Level Concern	Moderate	Moderate	Same

SE Analysis 1

The intended arm circumferences (13.5-21.5 cm VS about 15.50-25 cm) and cuff size (31X 8.3cm VS 30 X 7 cm) of the proposed and predicate device are different. This difference are very slight, and the cuff size is appropriate to the claimed intended wrist circumference per ANSI/AAMI/IEC 80601-2-30. Therefore, this point is considered as substantially equivalent.

SE Analysis 2

The pulse rate measurement range of the proposed is a little different compared with that of the predicate device. (40 – 199 bpm VS 30 – 180 bpm). The difference parts, 30-40 bpm and 180-199 bpm, are very rare and abnormal, and the the range is clearly stated on the label of the container and instructions manual, the operator can select whether to use this product per the actual conditions. Therefore, this difference is considered to be not affect the substantially equivalent conclusion.

The proposed device, U60 Series Wrist Electronic Blood Pressure Monitor, is determined to be Substantially Equivalent (SE) to the predicate device, Electronic Blood Pressure Monitor KD-795 (K070826), in respect of safety and effectiveness.